

**COMMONWEALTH OF MASSACHUSETTS
105 CMR: DEPARTMENT OF PUBLIC HEALTH**

105 CMR 180.000: THE OPERATION, APPROVAL, AND LICENSING OF CLINICAL LABORATORIES

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180.001: Purpose

The purpose of 105 CMR 180.000 is to establish the rules and regulations which clinical laboratories must follow in order to be operating and, if applicable, licensed in compliance with M.G.L. c. 111D.

180.002: Citation

105 CMR 180.000 shall be known as 105 CMR 180.000: The Operation, Approval and Licensing of Clinical Laboratories.

180.003: Scope and Application

105 CMR 180.000 establishes the minimum standards which all clinical laboratories including those which are part of a clinic or hospital licensed under M.G.L. c. 111 § 51, must meet in order to be operating in compliance with M.G.L. c. 111D. 105 CMR 180.000 further establishes pursuant to M.G.L. c. 111D the licensing requirements and enforcement procedures for all clinical laboratories which are not subject to licensure under M.G.L. c. 111 § 51.

180.004: Waiver of Requirements Imposed on Laboratories

(A) The Commissioner may waive the applicability to a particular laboratory of one or more of the requirements imposed on that laboratory by 105 CMR 180.000 if the Commissioner finds that:

- (1) compliance would cause undue hardship to the laboratory; and
- (2) the laboratory is in substantial compliance with the spirit of the requirement; and
- (3) the laboratory's non-compliance does not adversely affect the quality of the laboratory's test results.

(B) The laboratory shall provide to the Commissioner or his/her designee written documentation supporting its request for a waiver.

180.010: Definitions

In 105 CMR 180.000 the following words shall, unless the context requires otherwise, have the following meaning:

Accredited means the approval of schools, institutions, or programs, where appropriate, by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education, or, on an equivalent basis by the Department

Approved Clinical Laboratory means a clinical laboratory with a director at the level required by M.G.L. c. 111D § 7; or a director at the level of a hospital, a health department, university, medical research institution or military institution of the United States Government; or, a clinical laboratory certified under 42 C.F.R. 405.1310 *et seq.*: Subpart M. Conditions for Coverage of Clinical Laboratories; or a clinical laboratory licensed under the Clinical Laboratories Improvement Act of 1967; or a laboratory providing equivalent training or experience accepted by the Department.

Clinical Laboratory means a facility or place, however named, the purpose of which is to make biological, serological, chemical, immunohematological, cytological, pathological or other examinations of materials derived from a human body.

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Collection Station means a facility where materials or specimens are either withdrawn or collected from patients or assembled after being withdrawn or collected elsewhere from patients for subsequent delivery to a clinical laboratory for examination. A collection station is a facility which is maintained at a separate physical location not on the grounds or premises of the main licensed laboratory or institution which performs the testing.

Commissioner means the Commissioner of Public Health.

Company means a corporation, a partnership, an association, or an organized group of persons, whether incorporated or not.

Complex Laboratory means a test performed in a physician office which requires sophisticated technique, interpretation of multiple signals and/or proven technical skill. This test requires, but is not limited to one or more of the following steps:

- (1) highly skilled physical manipulation;
- (2) technique dependent steps in the testing, sampling or reading of results;
- (3) user programming of the device or devices;
- (4) detailed calculation of the results;
- (5) dilution of samples with chemically reactive substances;
- (6) preparation of reagents.

Each Day of Use means, for purposes of quality control, each eight hour shift or other regular shift acceptable to the Department within a clinical laboratory.

Exempt Test means a test performed in a physician office laboratory which is generally noninstrumental in nature, and the results of which are determined by observation of a visual signal.

Health Promotion Screening Program means a laboratory testing service which examines material derived from a human body for the purpose of promoting health awareness and education among the general public by early detection of disease and/or associated risk factors. Health promotion screening tests are not used for the purpose of providing clinical diagnosis or treatment to patients.

Histocompatibility Testing means any laboratory test procedure the purpose of which is to determine compatibility between a potential organ transplant donor and recipient or to test for a disease-associated antigen. A donor organ does not include blood or blood components.

Owner means any individual, partnership, group, firm or corporation holding either partial or complete ownership of or title to a laboratory.

Person and Whoever shall elude corporations, societies, associations, partnership an individual or his estate upon his death, and a political subdivision of the Commonwealth; but not an agency of the Commonwealth.

Personal and Direct Supervision means that a qualified general supervisor or supervisory cytotechnologist, where applicable, is on the premises and immediately available to the bench area when laboratory procedures are being performed.

Proficiency Testing Program means a proficiency testing program which has been approved by the Department. A complete list of proficiency testing programs approved by the Department shall be made available to all laboratories on an annual basis.

Radiobioassay means

- (1) an examination to identify radionuclides which are taken in by chronic or acute absorption, ingestion, or inhalation; and
- (2) following the administration of a radioactive material to a patient, the subsequent analysis of a body fluid, or excreta in order to evaluate body function.

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Satellite Laboratory means

- (1) a physician office laboratory maintained by three or more physicians performing simple or complex testing, which is located off the premises of the primary or parent office of the group practice and is located in a secondary office of the same group practice; or
- (2) a laboratory administered through a state sponsored program, which is located off the premises of the parent laboratory.

Simple Laboratory Test means a test performed in a physician office laboratory which may require a series of steps/reagent additions or instrumentation, and the results of which are generally determined by a visual signal, but which is not a complex laboratory test as defined in 105 CMR 180.010.

Subsequent to Graduation means laboratory training and experience in an approved clinical laboratory acquired after receipt of the degree or completion of the required academic study specified. For purposes of qualifying as a director (105 CMR 180.060), general supervisor (105 CMR 180.115), technical supervisor (105 CMR 180.125), or technologist (105 CMR 180.155), experience as a technologist in an approved clinical laboratory, which was gained prior to acquiring such degree or completing the required academic study, may be substituted on an equivalency basis of 1.5 years of such experience for every one year of post-degree training and experience; and experience as a general supervisor or technical supervisor in an approved clinical laboratory, which was gained prior to acquiring such degree or completing the required academic study, may be substituted on a one-for-one basis.

Substitution of Education for Experience means for a general supervisor (105 CMR 180.115) or technologist (105 CMR 180.155) that a minimum of 30 semester hours of credit from either an approved school of medical technology, or towards a bachelor's degree in chemical physical or biological science from an accredited institution is considered equivalent to 2 years of experience. Additional education shall be equated at the rate of 15 semester hours of credit for one year of experience.

180.030: Licensure and Approval

(A) Application. Clinical Laboratories functioning under the control of a hospital or clinic licensed pursuant to M.G.L. c. 111 § 51 shall apply for a certificate of approval. Any person or entity who operates a health promotion screening program shall apply for a letter of approval in accordance with 105 CMR 180.030(D). All other clinical laboratories shall apply for a license issued pursuant to M.G.L. c. 111D. Any laboratory which is accredited, certified or licensed by a program which is deemed equivalent to these regulatory standards by the Department will be considered to meet the requirements of 105 CMR 108.000. Any laboratory services not inspected and accredited, certified, or licensed by a deemed equivalent program shall comply with all requirements for licensure or approval.

All laboratories, including those which are inspected and accredited, certified or licensed by a deemed equivalent program, must comply with requirements set forth in 105 CMR 180.450, *et seq.* Proficiency Evaluation, and 105 CMR 180.044 Reporting of Infectious Diseases. All laboratories, including those which are inspected and accredited, certified or licensed by a deemed equivalent program, must comply with requirements set forth in 105 CMR 180.300: ***Special Requirements - Viral Serology (HIV Testing)***. Facilities requesting licensure or approval under 105 CMR 180.000 shall submit an application on a form approved by the Department

(B) Licenses. The Department shall issue two classes of licenses to laboratories which are not otherwise subject to licensure pursuant to the laws of the Commonwealth. The classes of licensure shall be known as "Limited" and "Full".

(1) Limited License:

(a) A limited laboratory license shall be issued to any qualified person who maintains a clinical laboratory and who meets one of the following requirements:

1. In the case of an independent clinical laboratory performs only those limited laboratory examinations approved by the Department
2. In the case of a physician office laboratory performs only those simple laboratory tests approved by the Department.

(b) A list of the approved laboratory examinations shall be available from the Department. The Limited Test List for independent laboratories and the Simple Test List for physician office

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laboratories approved by the Commissioner in consultation with the Department's Advisory Committee on Clinical Laboratories may be reviewed annually.

Notwithstanding the list of approved laboratory examinations for a limited license persons qualifying for a limited license shall perform only those examinations which are within the training and experience of the individual who will be performing the test

(c) Applicants who are determined to meet the requirements for a limited license shall in addition to the requirements of M.G.L. c. 111D, meet all of the following requirements:

1. Make available for review by the Department written policies and procedures for the collection and examination of specimens as well as detailed written procedures for the collection, transport and handling of those specimens which are referred to an outside laboratory.
2. Perform appropriate quality control and preventive maintenance, approved by the Department for all test procedures and equipment. Documentation demonstrating that the expected control reactions were obtained shall be maintained by the facility.
3. Participate satisfactorily in an approved proficiency testing program covering all laboratory specialties in which the laboratory is approved to perform tests. Criteria for participation and satisfactory performance shall be as stated below in 105 CMR 180.450.
4. Make available a permanent, identifiable area for the handling of specimens and safe storage of supplies and equipment
5. Properly date and enter all laboratory results into the patient's medical record.
6. Keep all records of laboratory testing and quality control for a minimum of 4 years.
7. Maintain records documenting the initial training of any individual who performs testing. Ongoing continuing education and training shall be provided to such individuals and evidence of successful completion of such education and training shall be maintained.
8. File an annual affidavit with the Department specifying the nature of all testing services, the individuals performing the tests, the individuals responsible for the accuracy of the tests, the methods of testing employed, the quality control practices employed and any other information required by the Department
9. A facility may enter into a written contract for the provision of all or part of the clinical laboratory services with a laboratory which is either licensed, approved or certified by the appropriate state or federal agencies. The facility must have detailed written procedures for the collection, transport and handling of all specimens being referred to such outside laboratory. The procedures shall be available for review by the Department.

(2) Full License:

- (a) A full laboratory license shall be required of any person who maintains a clinical laboratory which performs test procedures in addition to those approved by the Commissioner pursuant to 105 CMR 180.030(B)(1)(a).
- (b) A laboratory with a full license shall comply with these regulations, M.G.L. c. 111D, and any other applicable statutes or regulations.
- (c) Full licenses shall state the specialty areas in which a laboratory is qualified to deliver services.

(3) Renewal

Laboratories licensed pursuant to M.G.L. c. 111D shall be required to have their licenses, whether limited or full, renewed every two years.

(4) Fees

- (a) The fee for a limited license shall be \$100.00 for initial or renewal licensure.
- (b) The fee for a full license shall be \$300.00 for each specialty area for which a license is issued.

(C) Certificate of Approval. The Department shall issue two classes of certificates of approval to laboratories which are operating as part of a clinic or hospital licensed pursuant to M.G.L. c. 111, § 51. The classes of certificates of approval shall be known as "Limited" and "Full." The requirements for a limited certificate of approval shall be exactly the same as the requirements for a limited license as set forth in 105 CMR 180.030(B)(1). The requirements for a full certificate of approval shall be exactly the same as the requirements for a full license as set forth in 105 CMR 180.030 (B)(2). Certificates of approval shall be renewable every two years. There shall be no fee for certificates of approval. The enforcement procedures set forth in 105 CMR 180.035 shall not apply to laboratories which receive certificates of approval.

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(D) Letter of Approval

The Department shall issue a letter of approval to qualified health promotion screening programs that perform only those health promotion screening tests approved by the Department in consultation with the Department's Advisory Committee on Clinical Laboratories. A list of the approved health promotion screening tests shall be available from the Department. Letters of approval shall be renewable every two years. The requirements for a letter of approval shall be as follows.

- (1) The entity must establish and follow an appropriate procedure for performing the test. This procedure must include at a minimum the following information:
 - (a) specimen collection and preparation;
 - (b) materials and equipment required;
 - (c) steps to follow to perform the test;
 - (d) limitations of the procedure;
 - (e) cautions to be observed which may affect the test results;
 - (f) safety precautions to protect patients and testing personnel;
 - (g) normal range of results;
 - (h) results which require follow up with a physician;
 - (i) quality control procedures to be followed using appropriate reference materials;
 - (j) calibration and maintenance protocols; and
 - (k) a plan for remedial or corrective action to be followed in the event that quality control results do not fall within acceptable limits.
- (2) All analytical equipment used for the performance of tests (i.e., timers, detectors or meters) must be calibrated or checked as appropriate for the device.
- (3) All test reagents must be properly stored and may not be used beyond their expiration dates.
- (4) Each method must be tested with appropriate reference materials to assure accuracy and precision:
 - (a) Each qualitative method must be tested with a positive and negative control on each day of testing.
 - (b) Each quantitative method must be tested with a normal and abnormal or high and low control on each day of testing. In the event that only one control level is available, the control material must be tested after every 20 patient tests during the course of the day.
 - (c) The accuracy of the screening procedure must be verified by sending at least one previously tested specimen to a licensed laboratory on a semi-annual basis.
 - (d) All quality control tests must be performed at the location of (and prior to) each public screening.
 - (e) Remedial or corrective action must be taken in the event that quality control results do not fall within acceptable limits.
- (5) Quality control and calibration measures shall be recorded and documentation shall be maintained for one year.
- (6) All persons tested must be provided with a confidential written test result that includes pertinent educational materials including, but not limited to, the following information:
 - (a) the limitations of the test;
 - (b) the interpretation of the test result(s);
 - (c) associated risk factors;
 - (d) the need for physician follow-up; and
 - (e) a telephone number for additional information (if additional information is available).
- (7) All infectious or physically dangerous medical waste including blood saturated materials and sharps must be stored and disposed of in accordance with the requirements set forth in 105 CMR 480.000: *Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste: State Sanitary Code Chapter VIII*.
- (8) The entity must maintain records documenting the initial training of any individual who performs testing. Training programs should be established on a schedule that is specified by the Department. Ongoing continuing education and retraining shall be provided to such individuals if applicable or as needed. The training program must be taught by health professionals with experience in clinical detection, measurement and analysis appropriate for the screening services offered. Training programs should reference appropriate national standards as available. The program must include at a minimum:
 - (a) a thorough training on proper specimen collection;
 - (b) a thorough training in the content and application of the pertinent test protocols;

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- (c) a means for testing employee technique and proficiency in performing the test including retesting known samples; and
- (d) a thorough training on test limitations and potential errors, interpretation of results, associated risk factors, and appropriate need for physician referral.
- (9) All persons involved with the collection, handling and/or testing of specimens must conform with the "***Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers***" as issued by the Centers for Disease Control of the Department of Health and Human Services publication dated February, 1989 or as most recently updated. These guidelines require new gloves for the collection and processing of each specimen.
- (10) All puncture wounds resulting from specimen collection must be covered with a sterile gauze adhesive strip (bandage) following sample collection.
- (11) An application for approval shall include a list of health promotion screening sites, dates and period of time (if known). The Department must be notified prior to each health promotion screening event which is to take place in a location other than the location indicated when initial approval is sought. Such notification must be made at least five days prior to each event and must include the expected date, location and period of time.
- (12) At every public screening event the letter of approval issued by the Department must be conspicuously displayed.

(E) Classification of Specialties

- (1) Laboratories with a full license or certificate of approval may be licensed or approved to perform tests in the following specialty and sub-specialty areas:

<u>Specialty</u>	<u>Sub-Specialty</u>
Microbiology	Bacteriology Mycology Parasitology Virology Other Microbiology
Immunology	Syphilis Non-Syphilis Viral Serology (HIV Testing)
Clinical Chemistry	Routine Chemistry Endocrinology Toxicology Urinalysis Radioassay (In-Vitro) Immunochemistry Other Chemistry
Immunohematology	Blood Group and Rh Typing Rh Titers Cross-Matching (Non-transfusion purposes) Cross-Matching (Transfusion purposes - Sec 105 CMR 180.410(0(5)) Other Immunohematology
Hematology	Routine Hematology Cellular Studies Coagulation Other Hematology
Pathology	Diagnostic Cytology Histopathology Oral Pathology
Radiobioassay Cytogenetics	

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Histocompatibility Testing

(F) A specialty or sub-specialty area shall be included in the laboratory license or certificate provided that the laboratory supplies sufficient evidence to the Department that the laboratory functions actively in that specialty or sub-specialty and performs a reasonable number of tests to maintain its proficiency.

(G) Provisional Licenses and Certificates

(1) Notwithstanding any of the 105 CMR 180.030(A) through (F), the Department may issue a provisional license or certificate if it determines that the laboratory applicant does not meet every requirement for a full or limited license or certificate; provided that the laboratory has demonstrated to the Department's satisfaction a good faith intention to correct deficiencies; provided further that the Department finds that the laboratory provides reliable reports of examinations of specimens and presents satisfactory evidence that the requirements for full licensure or certification can and will be met within a six month period.

(2) A provisional license or certificate shall be for such a term as the Department deems appropriate, but in no event shall the term exceed six months.

(3) No laboratory shall be issued more than two consecutive provisional licenses or certificates.

(4) The fee for a provisional license, limited or full, shall be exactly the same as for a limited or full license as set forth in 105 CMR 180.030(B)(4). There shall be no fee for provisional certificates.

(H) The Department or its agents may make regular on-site visits to inspect the laboratory for licensure pursuant to M.G.L. c. 111D, § 2. or approval pursuant to M.G.L. c. 111 § 51 through 53.

180.031: Special Projects

The Department will consider proposals for special projects for the innovative delivery of clinical laboratory services. No such plan shall be implemented without prior written approval of the Department. Such plans shall be implemented only on an experimental basis and subject to renewal of the approval by the Department at such periods as the Department shall fix.

180.035: Enforcement Procedures

(A) Correction Orders and Administrative Reconsideration

(1) Whenever the Department finds upon inspection or through information in its possession that a clinical laboratory licensed or approved pursuant to c. 111D is not in compliance with a provision of M.G.L. c. 111D or a regulation promulgated thereunder, it may order the licensee or approved entity to correct such deficiency. The correction order shall include a statement of the deficiencies found, the provisions of law relied upon, and the period prescribed for correction, which shall be reasonable and, except in an emergency declared by the Commissioner, not less than 30 days after receipt of such order.

(2) The Department shall notify the licensee or approved entity of his right to administrative reconsideration of the correction order. The licensee or approved entity may within ten days of receipt of the order, file a written request with the Department for administrative reconsideration. The request shall clearly identify the licensee or approved entity, state the date and nature of the order, state the reason why the order should be rescinded or modified and shall be signed by either the licensee or approved entity or the director employed by the licensee or approved entity.

(3) The Department shall have ten days after receipt of the reconsideration request to act upon the request. Failure of the Department to grant, deny or otherwise act upon a reconsideration request within ten days after filing shall be deemed a denial.

(4) Upon expiration of a correction order, the Department may reinspect the clinical laboratory in order to determine compliance by the laboratory with the correction order. If the Department makes a determination of substantial non-compliance with the correction order, the Department may issue a Notice of Sanctions to the clinical laboratory. The Notice of Sanctions shall be subject to the procedures set forth in 105 CMR 180.035(C).

(B) License or Approval Modification Orders

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(1) The Department may order modification of a license or approval issued to a clinical laboratory if upon inspection or through other information in its possession, it determines that the laboratory is not able to or is not providing reliable reports of examinations pursuant to the terms of the license or approval. The license or approval modification order shall be for the purpose of enabling the laboratory to provide reliable reports and shall include a statement of the reasons for modification, the provisions of law relied upon and the date fixed for compliance, which shall be reasonable and, except in an emergency declared by the Commissioner shall be not less than 30 days after receipt of the order.

(2) The Department shall notify the licensee or approved entity of his right to an adjudicatory hearing under the provisions of M.G.L. c. 30A. The licensee or approved entity may file a written request for a hearing within 30 days of receipt of the notice or the right to a hearing shall be deemed to have been waived.

(3) The filing of a request for a hearing shall not operate as a stay of the compliance date of a license or approval modification order, but the Department shall stay the compliance date upon written request, except to the extent that a stay would jeopardize the public health or public safety. If after hearing the licensee or approved entity establishes that the order, or any portion thereof, is not warranted, the Department shall rescind or qualify the order as appropriate.

(C) Revocation of License or Approval and Other Administrative Sanction

(1) The Department may revoke the license or approval issued under M.G.L. c. 111D, § 5 or impose other appropriate administrative sanction upon a license or approval, or both, for conduct by or chargeable to him as follows:

(a) Failure to observe any term of such license or approval; or

(b) failure to meet any requirement for such license or approval established under M.G.L. c. 111D, § 5; or

(c) failure to observe any order made under authority of M.G.L. c. 111 D or under other statutory authority vested in the Department; or

(d) engaging in, or aiding, abetting, causing, or permitting any action prohibited under M.G.L. c. 111D, § 8; or

(e) engaging in or aiding any falsification of laboratory test results including the reporting of such false results to any test purchaser; or

(f) for conviction in a court of competent jurisdiction of any crime which directly or indirectly relates to the ownership or operation of a clinical laboratory licensed or approved under M.G.L. c. 111D; or

(g) other proper cause set forth in regulations promulgated pursuant to M.G.L. c. 111D.

(2) Prior to sanctioning a license or approval, the Department shall give the licensee or approved entity notice of the proposed action, notice of the charges against him, the provisions of law relied upon, and shall afford him the opportunity for a hearing under the provisions of M.G.L. c. 30A. The licensee or approved entity may file a written request for a hearing within 30 days of receipt of the notice or the right to a hearing shall be deemed to have been waived.

(3) If, after hearing, the Department finds that cause exists for imposition of a sanction, it may impose a lesser sanction than the proposed sanction if the lesser sanction is appropriate in the circumstances. Lesser sanctions may include, but shall not be limited to, either singularly or in combination: license or approval suspension, license or approval modification and fines. Fines imposed shall be in accordance with a schedule published by the Department which shall be available to the licensee or approved entity. In the event revocation is imposed, the licensee or approved entity shall be permitted a reasonable period to cease operation, but in no case less than 30 days after notice from the Department. In the event no timely appeal of the proposed sanction is filed by the licensee or approved entity, the proposed sanction shall be imposed as the final decision of the Department.

(D) Suspension of License or Approval

(1) The Commissioner may, at any time upon notice to the licensee or approved entity, whether a hearing has been first commenced or not, suspend his license or approval or issue such other preliminary order as the Commissioner considers appropriate for the protection of the health or safety of the public if he should find that either is in jeopardy.

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(2) A hearing pursuant to M.G.L. c. 30A shall be commenced within five days after such notice in any case of suspension without a prior hearing unless the licensee or approved entity shall request a postponement. The notice from the Commissioner shall include the charges against the licensee or approved entity, the provisions of law relied upon, the finding of the Commissioner and the date upon which the hearing shall commence.

(E) Hearing Procedure

All administrative hearings held pursuant to 105 CMR 180.000 shall be conducted under 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*.

180.040: Condition: General Requirements

Each laboratory licensed or approved by the Department shall meet the standards set forth in 105 CMR 180.041 through 180.044.

180.041: Standard - Responsibility of Owners

(A) The owner shall be responsible for the proper maintenance and ethical operation of the clinical laboratory and for any violations of 105 CMR 180.000 and other regulations. The Department shall be notified in writing within a 30-day period of changes in Director, General Supervisor, and Technical Supervisor. Significant changes in the physical facilities shall be reported to the Department within 30 days after initiation of such changes.

(B) The owner shall notify the Department 15 days in advance of any change in the location or ownership of a laboratory.

(C) The owner shall be responsible that the clinical laboratory is at all times under the direction of a Director acceptable to the Department. In the case where the Director is to be absent for more to the approval of the Department and shall so notify the Department in advance.

(D) The owner shall notify the Department in advance whenever the designated Director is expected to terminate his employment. Permission may be granted to continue operation of the laboratory for a time period not to exceed six calendar weeks after the termination of the Director and prior to the appointment of a new Director.

(E) The owner and director shall, if different persons, be jointly and severally responsible for the operation of the laboratory in compliance with the provisions set forth in 105 CMR 180.000 and with other pertinent regulatory and statutory requirements.

180.042: Standard - Collection Stations and Satellite Laboratories

(A) Collection Stations A clinical laboratory shall not represent or maintain a specimen collection station on behalf of any other clinical laboratory unless such laboratory, if in the Commonwealth, is licensed under M.G.L. c. 111D, § 5 or has been approved as part of a hospital or clinic licensed pursuant to M.G.L. c. 111 § 51 or unless such laboratory, if not in the Commonwealth, has been accredited or is licensed in accordance with federal law. No laboratory testing may be performed at a collection station unless a license or certificate issued pursuant to 105 CMR 180.030 has been obtained.

(1) Any permanent area other than the actual laboratory facility which is used for the collection of specimens by venipuncture shall be inspected prior to use and a written certificate of approval shall be issued by the Department. The licensee or director of a laboratory shall notify the Department in writing immediately when the operations of an approved blood collection station are about to terminate.

(2) An approved blood collection station shall meet all applicable requirements set forth in Conditions 105 CMR 180.250 (Management) and 105 CMR 180.040 (General) and shall possess as a minimum, a blood drawing chair or cot acceptable to the Department, a telephone, adequate hand washing and toilet facilities for employees and patients within the station and a written procedure manual detailing the steps to be followed in the event of an emergency. Approved blood collection stations shall be identified by signs and advertising in a manner which does not suggest that the station is a laboratory.

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No laboratory examinations shall be performed in a blood collection station other than the separation of plasma and serum and such other preparative procedures as the Department may allow.

(3) The director of the laboratory of which the approved blood collection station is a part shall be responsible for all aspects of the blood collection station, including without limitation, the physical plant, personnel, processing and transport of specimens. The director of the laboratory of which the approved blood collection station is a part (or his/her designee) shall be available to blood collection station personnel at all times during the operation of the station for personal or telephone consultation and shall make periodic personal inspections of the station to insure suitable handling of patients and specimens and to instruct the employees in such matters and in the most recent improvements in technique. The director of the laboratory of which the approved blood collection station is a part (or his/her designee) shall establish protocol for action in cases of emergency which must include, without limitation, the immediate availability of a physician or emergency medical service. Any technical employee of a blood collection station must be proficient in venipuncture, specimen processing as limited by 105 CMR 180.000, and emergency procedures required to aid a distressed patient

(B) Satellite Laboratories

(1) A satellite laboratory must independently meet all the requirements imposed on laboratories by 105 CMR 180.000 except that a satellite laboratory:

(a) may have the same clinical laboratory director and/or technical supervisor as the parent laboratory; and

(b) may store its records at the parent facility.

(2) A satellite laboratory shall have no separate articles of organization, or by-laws or other charter of its own, and no separate governing body, shareholders, members or officers.

(3) A satellite laboratory shall be inspected in conjunction with the licensure inspection of the parent laboratory.

(4) A satellite laboratory may only perform testing in specialties in which the parent laboratory is licensed using the same methodologies as the parent laboratory.

180.043: Standard – Advertising

(A) Advertising is permissible in professional media if it is of an ethical nature and does not contain misleading statements or unsubstantiated claims. Advertising to individuals in the general public is permitted so long as such advertising:

(1) does not misrepresent, by false statement, by omission of a material fact, or scheme, trick, or device, the category or categories of procedure performed at, or the service or services available at, the clinical laboratory;

(2) informs the public that Massachusetts law prohibits laboratories from performing tests without a written request from a licensed physician, dentist, or other authorized person; and

(3) conforms to all other Massachusetts laws and regulations.

Personal solicitation by an owner or his agent shall be considered advertising within the meaning of 105 CMR 180.043.

(B) Brochures or test listings distributed by the laboratory shall not contain lists of tests or services which are not performed on its own premises, unless the brochure or list indicates clearly that the tests so listed are performed elsewhere. Brochures or test listings shall be updated on a reasonable basis from time to time.

(C) Signs of a descriptive character designed to identify the laboratory premises or access thereto are permissible except when their content, size, or location is unethical or when they are determined by the Department to constitute a form of advertising to individuals in the general public which does not comply with 105 CMR 180.043(A).

180.044: Standard - Reporting of Infectious Disease

Clinical laboratories shall be responsible for reporting to the Department any result on a specimen that yields evidence significant from a public health standpoint of the presence or for the prevention, diagnosis, or control of any of those infectious diseases identified by the Department in conjunction with the Advisory Committee on Clinical Labs.

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(A) These reports shall be submitted on forms provided by the Department at intervals specified by the Department.

(B) The Department shall supply each responsible laboratory with guidelines indicating the specific laboratory evidences of the diseases which are required to be reported.

(C) Clinical laboratories making such reports shall not be held liable for having violated a trust or confidential relationship. The reports should be deemed confidential and not a public record within the meaning of M.G.L. c. 4, § 7(26).

180.045: Condition - Compliance with Federal, State and Local Laws

Each laboratory shall comply with all applicable federal, state and local laws. Such compliance shall include, at a minimum, the following:

(A) **Licensure or Certification**. All laboratories subject to regulation shall

- (1) be licensed, approved or certified according to applicable laws, and
- (2) have current approval by the federal, state or local agency responsible for licensing, approving or certifying the laboratory.

(B) **Licensure of Staff**. The director and all technical staff shall be licensed or registered in accordance with applicable laws;

(C) **Fire and Safety**. The laboratory shall be in conformity with all laws, ordinances and regulations relating to fire and safety.

180.050: Condition - Laboratory Director

Every person licensed or approved to maintain a clinical laboratory under 105 CMR 180.000 shall appoint an individual, who shall bear the title "Clinical Laboratory Director".

No individual so appointed shall serve as clinical laboratory director for more than three months unless the Department within that period shall certify that such person is qualified pursuant to 105 CMR 180.060.

180.060: Standard - Laboratory Director Qualifications

The minimum qualifications for a Clinical Laboratory Director shall be as follows:

(A) A physician who is certified in anatomical or clinical pathology by the American Board of Pathology or in at least one laboratory specialty by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Dermatology, or other national accrediting board acceptable to the department, or who possesses qualifications which the department considers equivalent to any such certification except that physicians certified by the American Board of Dermatology are restricted to director of a dermatology laboratory; or

(B) An individual who holds an earned doctoral degree, with a chemical, physical, or biological science as his major subject, from an accredited educational institution, and he is certified in at least one laboratory specialty by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the department, or he possesses qualifications which the department considers equivalent to any such certification; or

(C) An individual who has been responsible for direction of the technical and scientific operation of a clinical laboratory for at least 12 consecutive months at any time during the calendar years of 1971 through 1975, and who meets one of the following requirements:

- (1) He holds an earned master's degree, with a chemical, physical, or biological science as his major subject from an accredited educational institution and has had at least four years experience since graduation; or

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- (2) He holds an earned bachelor's degree, with a chemical, physical, or biological science as his major subject from an accredited educational institution and has had at least six years experience since graduation in a clinical laboratory; or
- (3) He has passed an examination conducted by or under the sponsorship of the United States Public Health Service, and approved by the Department as evidence of competence to direct the technical and scientific operation of a clinical laboratory; or
- (4) A physician who meets the following requirements:
 - (a) is a member of the group practice which is maintaining the laboratory exclusively in connection with the diagnosis and treatment of its own patients and the laboratory is performing only those test procedures which are included on the approved limited license test list;
 - (b) holds an earned bachelor's degree with a chemical, physical, or biological science as his/her major subject; and
 - (c) has at least one year of pertinent experience subsequent to graduation in a clinical laboratory with the range of testing at least as broad as the testing in the current laboratory.

180.070: Standard - Laboratory Director: Duties and Responsibilities

Each laboratory shall employ a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests. Such administration shall include, at a minimum, the following:

- (A) In no event shall any individual accept employment as a clinical laboratory Director at more than three clinical laboratories during the same period. The director may be employed on a full-time, or regular part-time basis.
- (B) The director shall, commensurate with the laboratory workload, spend an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and be readily available for personal or telephone consultation.
- (C) The director shall be responsible for ensuring the quality operation of the laboratory and the accuracy of test results.
- (D) The director shall be responsible for the employment of qualified laboratory personnel and their in-service training.
- (E) If the director is continuously absent for more than six weeks the laboratory shall temporarily employ a qualified substitute director who shall assume responsibility for the functions of the laboratory.

180.100: Condition - Laboratory Supervision

The clinical laboratory shall be supervised by qualified personnel. There shall be two categories of required supervisors: General Supervisors and Technical Supervisors.

180.105: Standard - General Supervision

- (A) A qualified general supervisor shall be on the laboratory premises and immediately available to the bench area during all hours in which tests are being performed.
- (B) A qualified general supervisor shall not be required to be on the premises during shifts or working periods when only emergency (or STAT) work is being performed. When such emergency (or STAT) testing is performed, it shall be performed by a technologist qualified to perform such tests, and the next regularly scheduled supervisor who is responsible for the results of the work shall review them. A written record of the actual review shall be maintained.
- (C) With respect to the specialty of diagnostic cytology, cytotechnologists shall not examine slide preparations unless a supervisor who qualifies pursuant to the provisions of 105 CMR 180.115(H) or 180.125(B)(1) or (B)(3) is on the premises at all times.

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(D) A general supervisor may also be a technical supervisor in those specialties in which the general supervisor qualifies.

180.110: Standard - Technical Supervision

The laboratory shall perform only those laboratory procedures and tests that are within the specialties and subspecialties in which the laboratory is licensed and for which the laboratory has a qualified supervisor.

180.115: Standard - General Supervisor Qualifications

The General Supervisor shall meet one of the following requirements:

(A) Be an individual who qualifies as a laboratory Director under 105 CMR 180060(A), (B), or (C).

(B) Be a physician or have an earned doctoral degree from an accredited institution with a major in one of the physical, chemical or biological sciences, and have two years of pertinent full-time laboratory experience subsequent to graduation covering all of the laboratory areas to be supervised.

(C) Have earned a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences, and have three years of pertinent full-time laboratory experience subsequent to graduation covering all areas to be supervised.

(D) Have a bachelor's degree in medical laboratory science and have three years of pertinent full-time laboratory experience subsequent to graduation covering all of the laboratory areas to be supervised.

(E) Have a bachelor's degree in chemical, physical or biological science, and have four years of pertinent full-time laboratory experience subsequent to graduation covering all areas to be supervised.

(F) For a specialty laboratory (i.e., a laboratory that performs tests only in a single specialty), have a bachelor's degree in that specialty area, and have three years of pertinent full-time experience subsequent to graduation covering the specialty to be supervised. An individual who possesses an earned bachelor's degree in a physical, chemical or biological science and who has earned at least 24 semester hours from an accredited institution in a specialty which was not his major field of study shall be deemed to have earned the equivalent of a degree in that specialty.

(G) Have achieved a satisfactory grade in a proficiency examination offered either by the Public Health Service, Department of Health and Human Services, or approved by the Department; and have six years of pertinent full-time experience in an approved clinical laboratory covering all of the laboratory areas to be supervised.

(H) With respect to the specialty of diagnostic cytology:

(1) Is qualified as a Cytotechnologist pursuant to 105 CMR 180.165(A) and has three years of pertinent full-time experience in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding ten years; or

(2) Is qualified as a Cytotechnologist pursuant to 105 CMR 180.165(B) and has an additional four years of pertinent full-time experience in a laboratory directed by or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding ten years; or

(3) Is qualified as a Cytotechnologist pursuant to 105 CMR 180.165(B) and has an additional four years of pertinent full-time experience in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding ten years.

(I) With respect to individuals first qualifying prior to January 1, 1985, have had at least four years of documented pertinent full-time experience in an approved clinical laboratory including two years as a General Supervisor within the preceding ten years.

(J) With respect to individuals first qualifying prior to January 1, 1985, have had at least six years of

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documented experience as a laboratory technologist in an approved clinical laboratory within the preceding ten years.

(K) Individuals qualifying as Technologist pursuant to the provisions of 105 CMR 180.155(E), (F) or (G) may qualify as a General Supervisor provided they have at least an additional three years of documented experience as a laboratory technologist in an approved clinical laboratory within the preceding ten years.

180.120: Standard - General Supervisor Duties and Responsibilities

The qualified general supervisor shall, under the general directions of the laboratory director;

- (A) Supervise technical personnel and reporting of findings;
- (B) Perform tests requiring special scientific skills; and
- (C) Assume such other administrative responsibilities as are delegated by the director.

180.125: Standard - Technical Supervisor Qualifications

A clinical laboratory shall have one or more individuals who qualify as a Technical Supervisor for each specialty area in which the laboratory is licensed to perform tests. The Director and/or the General Supervisor may qualify as the Technical Supervisor in one or more of the specialties, provided he meets the following criteria:

- (A) For all specialties except pathology:
 - (1) Qualifies as a laboratory Director or General Supervisor under 105 CMR 180.060(A), 180.060(B), 180.060(C)(1), 180.115(B), or 180.115(C), and has two years of full-time experience subsequent to graduation in the specialty for which is to be qualified; or
 - (2) Qualifies as a Director or General Supervisor under 105 CMR 180.060(C)(2), 180.115(D), 180.115(E), or 180.115(F) and has four years of pertinent full-time experience subsequent to graduation in the specialty for which is to be qualified; or
 - (3) Qualifies as a laboratory Director or General Supervisor under 105 CMR 180.060(C)(3), 180.115(G), 180.115(I), or 180.115(J), and has six years of pertinent full-time experience in an approved clinical laboratory in the specialty for which he wishes to be qualified.
- (B) For the specialty of pathology:
 - (1) Pathology (histopathology, diagnostic cytology, and oral pathology). Is a physician certified in anatomical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification (board eligible).
 - (2) Histopathology: Sub-specialty of Skin Pathology. Is a physician certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).
 - (3) Diagnostic Cytology. Is a physician certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are equivalent to those required for certification (board eligible).
 - (4) Oral Pathology. Is a dentist who is certified in oral pathology by the American Board of Oral Pathology or possesses qualifications which are equivalent to those required for certification (board eligible).

180.130: Standard - Technical Supervisor: Duties and Responsibilities

The technical supervisor for each specialty shall spend an adequate amount of time in the laboratory to supervise the technical performance of the staff in the specialty and be readily available for personal or telephone consultation.

180.150: Condition - Technical Personnel

A clinical laboratory shall have a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

180.155: Standard - Technologist: Qualifications

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Each clinical laboratory technologist shall meet one of the following criteria:

(A) Have earned a bachelor's degree in medical laboratory science from an accredited college or university, the degree program shall have included a one year structured clinical laboratory experience in either

- (1) the general areas of a clinical laboratory, or
- (2) in a specialty area; or

(B) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, have at least one year of relevant full-time laboratory experience and/or training subsequent to graduation in the specialty or subspecialty in which the individual performs tests; or

(C) Have successfully completed three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical laboratory science accredited by an accrediting agency approved by the Department, and have successfully completed a course of training of at least 12 months in such a school which included structured clinical laboratory experience in either

- (1) general areas of a clinical laboratory, or
- (2) in a specialty area; or

(D) Have successfully completed three years of academic study (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses:

(1) For those whose training was completed prior to July 1, 1980, at least 24 semester hours must have been in relevant chemistry and biology courses of which

- (a) at least six semester hours were in inorganic chemistry and at least three semester hours were in other chemistry courses; and
- (b) at least 12 semester hours in biology courses pertinent to the medical sciences; or

(2) For those whose training was completed after July 1, 1980,

- (a) have a minimum of 16 semester hours in chemistry which included at least six semester hours in inorganic chemistry which are acceptable toward a major in chemistry; and
- (b) 16 semester hours in biology courses which are relevant to the medical sciences and are acceptable toward a major in the biological sciences; and
- (c) three semester hours of mathematics; and

(3) Have at least one year of experience and/or training subsequent to completion of the academic study requirement, covering several fields of medical laboratory work of such quality as to provide him with education and training in medical technology equivalent to that described in 105 CMR 180.155(A) and (B); or

(E) Have successfully completed two years of academic study (a minimum of 60 semester hours or equivalent) before September 15, 1963, in an accredited college or university which met the specific requirements for entrance into a school of medical laboratory science accredited by an accrediting agency approved by the Department, and have successfully completed a course of training of at least 12 months in such a school which included structured clinical laboratory experience in either:

- (1) general areas of a clinical laboratory, or
- (2) in a specialty area; or

(F) Have successfully completed

(1) 60 semester hours of academic study including chemistry and biology, and

(2) have successfully completed either

- (a) a structured curriculum in medical laboratory techniques at an approved institution, or
- (b) an associate degree based upon a course of study including those subjects from an accredited institution, and

(3) have at least two years of documented clinical laboratory experience subsequent to graduation; or

(G) Have successfully completed

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- (1) 60 semester hours of academic study including chemistry, biology and/or relevant scientific courses,
and
 - (2) have at least four years of documented clinical laboratory experience subsequent to graduation; or
- (H) Have achieved a satisfactory grade in a proficiency examination offered either by the Public Health Service, Department of Health and Human Services or approved by the Department; or
- (I) With respect to individuals applying prior to January 1, 1985, the technologist shall
- (1) have been performing the duties of a clinical laboratory technologist at any time between July 1, 1973, and January 1, 1985, and
 - (2) have at least two years of documented experience as a technologist in an approved laboratory; or
- (J) With respect to individuals applying prior to January 1, 1985, the technologist shall
- (1) have performed the duties of a clinical laboratory technician or technician trainee at any time between July 1, 1973, and January 1, 1985, and
 - (2) have at least four years of documented clinical laboratory experience in an approved clinical laboratory.

180.160: Standard - Technologist: Duties and Responsibilities

The laboratory shall employ a sufficient number of clinical laboratory technologists and/or cytotechnologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment.

(A) The clinical laboratory technologists shall perform tests requiring the exercise of independent judgment and responsibility with minimal supervision by the director or supervisors only in those specialties or subspecialties in which the laboratory technologists are qualified by education, training, and experience.

(B) Specialties in which the clinical laboratory technologist is not qualified by education, training, or experience shall be performed only under the direct supervision of the laboratory supervisor or qualified technologist

(C) Clinical laboratory technologists shall be present in sufficient number to adequately supervise the work of technicians and trainees.

180.165: Standard - Cytotechnologist: Qualifications

Each Cytotechnologist shall meet one of the following requirements:

- (A) Have successfully completed two years in an accredited college or university with at least 12 semester hours in science, eight hours of which were in biology, and
- (1) have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by the Department, or
 - (2) have received six months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the Department and six months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal six months of training, or
- (B) Prior to January 1, 1985 have graduated from high school, completed six months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and completed two years of full-time supervised experience in cytotechnology; or
- (C) Have achieved a satisfactory grade in a proficiency examination offered by the Public Health Service, Department of Health and Human Services or approved by the Department

180.170: Standard - Cytotechnologist: Duties and Responsibilities

A Cytotechnologist shall be qualified by education, training and experience, to perform tests requiring the exercise of independent judgment and responsibility with minimal supervision by the

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director or supervisors. The Cytotechnologist shall perform tests only in those specialties or subspecialties in which he is qualified.

(A) Tests in specialties in which the clinical laboratory Cytotechnologist is not qualified by education, training, or experience shall be performed only under the direct supervision of the laboratory supervisor or a qualified technologist

(B) An individual qualified as a Cytotechnologist solely under 105 CMR 180.165 of this section may supervise technicians and trainees only in the specialty of cytology.

180.180: Standard-Technician: Duties and Responsibilities

Clinical laboratory technicians shall be employed in sufficient numbers to meet the workload demands of the laboratory and shall function only under direct supervision of a clinical laboratory technologist.

(A) Each technician shall perform only those clinical laboratory procedures which require a degree of skill and judgment commensurate with the education, training, and technical abilities of the technician.

(B) Clinical laboratory technicians shall perform procedures under the supervision of a qualified laboratory technologist, supervisor, or director.

180.190: Standard - Technologist Trainee: Duties and Responsibilities

Technologist trainees may perform procedures for which they have received specific technical training under the personal and direct supervision of a qualified supervisor or technologist

180.200: Standard - Training Programs

Training programs required for trainee-level personnel shall be structured so as to insure that they will produce individuals who can adequately perform duties at the technologist level. The director and supervisors shall actively provide for the development of trainees by formulating a structured program for the training. The laboratory shall have a means for examining the proficiency of the trainee and for providing records of the trainee's progress. Any laboratory employing trainees shall submit a written plan for the training of the Department for approval. The laboratory should consider the following factors when designing the training program: size of the laboratory, type of tests performed, number and qualifications of all personnel and the individual trainee's ability and needs.

180.250: Condition - Clinical Laboratory Management

The clinical laboratory shall maintain records and facilities which are adequate and appropriate for the service offered.

180.255: Standard - Laboratory Procedure Manual

(A) There shall be available at all times, in the immediate bench area, to personnel engaged in examining specimens and performing related procedures within a category (e.g., clinical chemistry, hematology, pathology, etc.), current laboratory manuals or other complete written descriptions and instructions for all automated and manual test procedures which are performed by the laboratory. Procedures shall include:

- (1) The analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory review;
- (2) Reagents;
- (3) Control and calibration procedures;
- (4) Pertinent literature references. Textbooks may be used as supplements to such written descriptions but shall not be used in lieu thereof. Each procedure shall be reviewed and dated by the technical supervisor at least annually. Written approval shall be given by the director or supervisor of all changes in laboratory procedures.

(B) Procedures which assure a reasonable turnaround time for all test results and provide for alternative testing mechanisms in the event that equipment or methods become inoperable shall be established for each test performed in the laboratory.

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180.260: Standard - Facility Management

Space and facilities shall be adequate to properly perform the services which are performed in or offered by the laboratory. Such space and facilities shall include, at a minimum, the following:

- (A) Workbench space shall be ample, well-lighted, and convenient to sink, water gas suction and electrical outlets as necessary.
- (B) Work areas shall be arranged so as to minimize problems in transportation and communication.
- (C) The laboratory shall be properly vented.
- (D) Volatile chemicals and inflammable solvents shall be properly stored in areas where ignition is unlikely and restricted from open flame or heat.
- (E) Temperature and humidity shall be controlled within those limits which are necessary for proper performance of tests and proper operation of laboratory instruments.
- (F) Appropriate enclosures, such as fume hoods and biological safety cabinets shall be utilized when handling hazardous materials.
- (G) Adequate fire precautions and occupational safety and health laws shall be posted in areas frequented by and visible to employees. The precautions and laws shall be known and observed by laboratory employees to insure that there is freedom from unnecessary physical chemical, biological and electrical hazards.
- (H) The laboratory shall maintain a sanitary environment.

180.265: Standard - Collection of Specimens

No person other than a licensed physician or an individual authorized by a qualified laboratory director or individual otherwise authorized by state law or regulation may collect blood or other specimens from a patient.

180.270: Standard - Sterilization

Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall not be reused unless they are properly sterilized prior to each use and wrapped in a manner which will insure that they remain sterile until used.

- (A) Appropriate sterilization and disinfection techniques shall be utilized, as required for tests performed on potentially contaminated material and for the protection of laboratory personnel.
- (B) Disposable syringes, needles, pipettes, Petri dishes, and other disposable items shall be appropriately discarded immediately after use.
- (C) Records shall be kept which indicate that each sterilizing cycle contains a device which indicates proper sterilization was carried out.
- (D) Proper operation of the autoclave shall be checked monthly with viable spores or appropriate indicators.

180.275: Standard - Disposal of Medical Waste

Licensing regulations governing the disposal of infectious or physically dangerous medical or biological waste are set forth in 105 CMR 480.000: *Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste: State Sanitary Code Chapter VIII* which is incorporated herein by reference.

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180.280: Standard - Examinations and Reports

The laboratory shall examine specimens only at the written request of a licensed physician, dentist, osteopath, chiropractor, nurse practitioner, physician's assistant, or other person authorized by M.G.L. c. 112 to use the report of laboratory examinations. Reports shall be delivered only to those authorized by law to receive such results unless such examination was made for the sole purpose of accuracy or sufficiency of the procedures or equipment of a clinical laboratory and by instruction of the director of such laboratory.

(A) If a patient is sent to the laboratory, a written request for the desired laboratory procedures shall be obtained by the laboratory from a person authorized by law to use findings of laboratory examinations.

(B) A specimen delivered to a laboratory shall be accompanied by a written request.

(C) A laboratory receiving reference specimens from another laboratory shall report back to the referring laboratory which submitted the specimens.

180.285: Standard - Specimen Records

The laboratory shall maintain a record indicating the daily accession of specimens, each of which shall be numbered or otherwise appropriately identified. Records shall contain the following information:

(A) The laboratory number or other identification of the specimen.

(B) The name and other identification of the person from which the specimen was taken.

(C) The name of the licensed physician, other authorized person or clinical laboratory which submitted the specimen.

(D) The date the specimen was collected by the physician or other authorized person.

(E) The date the specimen was received in the laboratory.

(F) The condition of unsatisfactory specimens when received (e.g. broken, leaked, hemolyzed, turbid, etc).

(G) The type of test performed.

(H) The date the test was performed and the name or initials of the person performing the test.

(I) The results of the laboratory test or cross-reference to results and the date of reporting.

(J) The name and identification of the laboratory the specimen is referred to if the procedure is not performed on the premises.

180.290: Standard - Laboratory Report and Record

The laboratory report shall be sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result shall be preserved by the laboratory for a period of at least four years after the date of submittal of the report. Minimum requirements are as follows:

(A) The final laboratory report shall bear the name or identification of the laboratory performing the test

(B) The laboratory director is responsible for the laboratory report and for maintaining the confidentiality of patient information and results of testing and for maintaining within the laboratory the confidentiality of patient information and results of testing.

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(C) Duplicate copies or a suitable record of laboratory reports shall be filed in the laboratory in a manner which permits ready identification and accessibility.

(D) Tissue pathology reports shall utilize acceptable terminology of a recognized system of disease nomenclature.

(E) The result of laboratory tests, including procedures or transcripts of results, shall not be sent directly to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

(F) Pertinent "reference" ranges as determined by the laboratory performing the tests shall be available to the legally authorized individuals requesting such tests.

(G) All laboratories shall provide a system designed to assist both the laboratory and the physician in the detection of matrix errors which affect all clinical laboratory tests performed. This system shall include the detection of matrix errors due to interfering substances of both endogenous nature (e.g. metabolites) and exogenous nature (e.g. drugs).

(H) A list of tests performed in the laboratory, analytical methods for each and a basis for the listed "reference" range shall be maintained in the laboratory. The list shall be made available to any authorized individual ordering an examination upon request.

(I) If the laboratory refers specimens to another laboratory, the laboratory receiving the specimens shall meet the applicable conditions in state or federal laboratory certification or licensure programs.

(J) Each authorized person ordering an examination shall be notified if the specimen is referred to another laboratory. Such notice shall show the name, address and other relevant identification of the laboratory to which the specimen is referred. If the authorized person so requests, the referring laboratory may allow the testing laboratory to report directly to the authorized person who originally requested the test. In the event of such direct reporting the testing laboratory shall send a duplicate of the report to the referring laboratory.

180.295: Standard - Personnel Policies

Each laboratory shall maintain written personnel policies, practices, and procedures that adequately support sound laboratory practice. The policies, practices and procedures shall include, at a minimum, the following:

(A) Current employee records shall be maintained and include a resume of each employee's training, experience, duties, and date or dates of employment.

(B) Evidence of adequate health supervision of employees, such as results of pre-employment physical examinations, including chest X-rays, immunization records, and records of all illnesses and accidents occurring on duty shall be maintained.

(C) Work assignments shall be consistent with qualifications.

180.300: Standard - Special Requirements - Viral Serology (HIV Testing)

(A) The laboratory shall reexamine every positive patient specimen and conduct a confirmatory test (different from the first and having greater specificity) or arrange for a confirmatory test to be conducted when a positive specimen is found

(B)(1) Pursuant to St. 1986, c. 241 both the identity of the subject of HIV tests and the test results are confidential and may not be released to anyone except the subject of the test without first receiving the subject's written consent

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(2) The laboratory shall maintain written procedures which protect the identity of the subject while the specimen is in process and ensure that the results are disclosed only to the patients' physician, in accordance with 105 CMR 180.290(E).

(C) The laboratory shall maintain written procedures which ensure that before the test is performed a form is included in the file which indicates that the patient has given written consent for the test based on an explanation of the following:

- (1) the voluntary nature of the procedure for patients who are not blood donors;
- (2) the purpose of the test;
- (3) an interpretation of the test and significance of test results, including the limitations;
- (4) the availability of additional information and counseling as necessary.
- (5) the fact that the test has been ordered and that the results will be recorded in hospital record.

(D) The clinical laboratory shall forward to the Department for approval a copy of the procedures developed in accordance with 105 CMR 180.300(A) through (C) together with its application, pursuant to 105 CMR 180.030, to perform tests in Viral Serology.

(E) In addition to 105 CMR 180.300(A) through (D), if a clinical laboratory operated by a hospital or clinic performs the HIV test for other than purposes of blood donor screening, there must be written documentation that the test has been ordered consistent with criteria established by an internal review mechanism within the hospital or clinic. Internal review shall focus on the factors set forth in 105 CMR 180.300(C).

(F) When a licensed laboratory acts as a collection station for specimens to be examined by a laboratory which is not subject to 105 CMR 180.000, it shall conform to the requirements set forth in 105 CMR 180.300(B) through (E).

180.350: Condition - Quality Control

Quality controls imposed and practiced by a laboratory shall provide for and assure maximum reliability of test results as evidenced by the following:

180.355: Standard - Evaluation of Equipment, Methods, Reagents

Each laboratory shall maintain records to assure that the following practices are performed:

- (A) Preventive maintenance, periodic inspection, and testing for proper operation of equipment and instruments as may be appropriate;
- (B) Validation of methods;
- (C) Evaluation of reagents and volumetric equipment;
- (D) Surveillance of results; and remedial action to be taken in response to detected defects.

180.360: Standard - Adequacy of Facilities, Equipment, Methods

Adequacy of facilities, equipment, instruments, and methods for performance of the procedures or categories of procedures shall include the following:

- (A) Proper lighting for accuracy and precision;
- (B) Convenient location of essential utilities;
- (C) Monitoring of temperature-controlled spaces and equipment, including water baths, incubators, sterilizers, and radioactivity counting equipment, with respect to all critical operating characteristics.

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(D) Evaluation of analytical measuring devices, such as photometers and radioactivity counting equipment, with respect to all critical operating characteristics.

180.365: Standard – Labeling

All reagents and solutions shall be labeled to indicate identity, and when significant, titer, strength or concentration, recommended storage requirements, preparation and expiration dates, and other pertinent information. Materials of substandard reactivity and deteriorated materials shall not be used.

180.375: Standard – Quality Control Records

Records reflecting dates and, where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, changes, and dates of changes shall be maintained and available to laboratory personnel and to the Department.

180.380: Standard - Surveillance by the General Supervisor

The quality control program shall be under the daily supervision of the general supervisor and shall be formally reviewed at least monthly by the technical supervisor(s).

180.385: Standard – Instructions for Collection, Preservation, Transportation

(A) The laboratory shall provide and make available instructions for proper collection, preservation, and transportation of specimens sufficiently stable to provide accurate and precise results suitable for clinical interpretation. This shall apply to specimens referred to other laboratories for testing as well as to tests performed on-site.

(B) The laboratory shall establish criteria and implement procedures for the rejection of specimens not collected, preserved, or transported properly.

(C) Collection of specimens shall be defined in the Procedure Manual of the hospital, clinic, or clinical laboratory.

180.390: Standard – Specialty Areas

Provision shall be made for an acceptable quality control program covering all types of accuracy, measurement of precision, and detection of error. The program shall include, but not be limited to, the following:

180.395: Standard - Microbiology: Quality Control

Chemical and biological solutions, reagents, and antisera shall be tested and inspected as specified below for reactivity and deterioration using positive and negative control organisms. The following requirements apply to the specialties of Bacteriology, Mycology, Parasitology, and Virology:

(A) Materials which shall be tested and inspected on each day of use include:

- (1) Media and discs used for antibiotic susceptibility testing;
- (2) Reagents and solutions used in the performance of conventional biochemical testing;
- (3) Stains (exception - Gram Stain).

(B) Materials which shall be tested and inspected each week of use and when a new vial or container is opened include:

- (1) Antibiotic discs (exception: antibiotic susceptibility discs);
- (2) Chemical strips;
- (3) Gram Stain materials.

(C) Materials which shall be tested and inspected each month of use and when a new vial or container is opened include:

Antisera.

(D) Materials which shall be tested and inspected when each new batch or shipment is received include:

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- (1) Tube and plate media;
- (2) Gram negative identification sets.

(E) Bacteriology and Mycology. Staining materials shall be tested for intended reactivity by concurrent application to smears of micro-organisms with predictable staining characteristics. Each batch of medium shall be tested before or concurrently with use with selected organisms to confirm required growth characteristics, selectivity, enrichment, and biochemical response.

(F) Parasitology. A reference collection of slides, photographs, or gross specimens of identified parasites shall be available and used in the laboratory for appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor.

(G) Virology. Systems for the isolation of viruses and reagents for the identification of viruses shall be available to cover the viruses for which services are offered. Records shall be maintained which reflect the systems used and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results. If serodiagnostic tests for virus diseases are performed, requirements for quality control as specified for serology shall apply.

180.400: Standard-Immunology: Quality Control

(A) Serologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or controls of graded reactivity such as weak positive controls, plus a negative control in order to detect variations in reactivity levels.

(B) Serum controls shall be used to detect the presence of non-specific reactions where applicable.

(C) Controls for all test components (antigens, complement, erythrocyte indicator systems etc.) shall be employed to insure reactivity and uniform dosage. Test results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.

(D) Each new lot of reagent or kits shall be tested concurrently with one of known acceptable reactivity with positive and negative serum samples before the new reagent or kit is placed in routine use.

(E) Equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to those recommended in the "*Manual of Tests for Syphilis 1969*" U.S. Public Health Service Publication No. 411, January 1969, as revised.

180.405: Standard - Clinical Chemistry: Quality Control

(A) Each instrument or other device shall be recalibrated or rechecked at least once on each day of use.

(B) At least one standard and one reference sample (control) shall be included with each batch of unknown specimens where such standards and reference samples are available.

(C) Control limits for standards and reference samples shall be recorded and available for review. Records shall also include the course of action to be instituted when the results are outside the acceptable limits.

(D) Screening or qualitative chemical urinalysis shall be checked daily by use of positive and negative reference samples.

180.410: Standard - Immunohematology: Quality Control

(A) ABO Typing

- (1) ABO Typing shall be performed by testing patient red cells with anti-A and anti-B serums licensed under 42 CFR Part 73, using the technique for which the serum is specifically designed to be effective.

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For confirmation of ABO grouping, the patient serum shall be tested with known Group A red cells or a red cell pool prepared from at least five known Group A individuals and Group B red cells.

(2) Any discrepancy between results of patient red cell and serum typings shall be resolved before the blood type is reported.

(B) Rh Testing

(1) The D type shall be determined by testing patient red cells with anti-D typing serum licensed under 42 CFR Part 73, using the technique for which the serum is specifically designed to be effective. All D negative donor cells shall be tested for the Du variant. A control system of the patient's cells suspended as for the D test and reagent control serum produced by the anti-D manufacturer shall be employed for each D test and Du variant test.

(2) If the D test is negative, the Du test shall be reported as positive, negative, or not performed.

(C) General

(1) The potency and reliability of reagents (antisera, known test cells, and antihuman globulin which are used for ABO grouping, RH typing, anti body detection and antibody identification) shall be tested for reactivity on each day of use. If a new lot of reagents is opened after the daily testing has been completed, the quality control testing must be repeated using the new lot of reagents.

(2) Determination of optimum time of centrifugation for each media or procedure employed (i.e. saline, and albumin, and saline washing) shall be made semi-annually.

(3) Coombs control cells shall be added to each tube giving a negative reaction in the antihuman globulin (Coombs) phase and shall give a macroscopically positive reaction.

(4) Patient samples obtained within the previous 48 hours shall be used if the test is for complement dependent antibodies.

(5) Any laboratory performing immunohematologic testing and cross-matches on samples or units which will be used for transfusion purposes shall be in compliance with 105 CMR 135.000: *Use of Blood, Blood Components, and Derivatives for the Purpose of Transfusion*.

180.415: Standard - Hematology: Quality Control

(A) Instruments and other devices used in hematological examination of specimens shall be checked for calibration as may be appropriate, during each day of use.

(B) Each procedure for which standards and controls are available shall be rechecked each day of use with standards or controls of two different levels for each parameter measured.

(C) At least two reference control materials of different levels shall be included for each day of testing and when each new vial of coagulation testing reagent is used.

(D) Reference materials, such as hemoglobin pools and stabilized cells, shall be tested at least once each day of use to insure accuracy of results.

(E) The accuracy and precision of blood cell counts, hematocrit and hemoglobin measurements shall be tested each day of use.

180.420: Standard - Exfoliative Cytology, Histopathology, Oral Pathology: Quality Control

(A) Exfoliative Cytology

(1) The Technical Supervisor or the Cytology General Supervisor shall re-screen for proper staining and correct interpretation at least a 10% random sample of gynecological smears which have been interpreted to be in one of the benign categories.

(2) All gynecological and non-gynecological smears interpreted to be in the "suspicious" or positive categories by screeners shall be confirmed and the report shall be signed by a physician qualified in anatomic pathology or cytology.

(3) All negative non-gynecological cytological preparations, shall be confirmed and signed by the Technical Supervisor or Cytology General Supervisor.

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- (4) Automated methods shall provide quality control similar to that provided in other automated laboratory procedures.
- (5) All smears shall be retained for a minimum of seven years from date of examination.
- (6) The Technical Supervisor for Cytology shall spend time working in the laboratory in proportion to the volume of cytology cases screened.
- (7) A quality control system shall be in place to assure and document the proficiency of all levels of personnel responsible for screening smears.
- (8) The Technical Supervisor for Cytology shall be available at the laboratory site on a regular basis to review and report on specimens and to review all components of the quality control system.

(B) Histopathology and Oral Pathology

- (1) All special stains shall be controlled for intended reactivity by use of positive slides.
- (2) Stained slides shall be retained for a minimum of 7 years from date of examination. Blocks shall also be retained for a minimum of 7 years from such date.
- (3) Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and the report has been signed by a physician qualified in anatomic pathology or oral pathology.

180.425: Standard - Radiobioassay: Quality Control

The counting equipment shall be checked for stability at least once on each day of use, with radioactive standards or reference sources. For each method, records which document the routine precision and the recalibration schedule shall be maintained and be available to the laboratory staff and the Department.

180.430: Standard - Histocompatibility: Quality Control

In addition to the standards for quality control in immunohematology (105 CMR 180.410) and immunology (105 CMR 180.400), which are applicable to the histocompatibility testing laboratory, the histocompatibility testing laboratory shall use the following control systems and validation methods for the performance of tests:

(A) Renal Allotransplantation

- (1) Crossmatching of potential recipients and donors before transplantation is performed with one or more of the more sensitive techniques using the most reactive and most recent patient sera;
- (2) HL-A serologic typing of both donor and recipient which include at least those antigens detectable with serum capable of defining the same antigens as those definable by the National Institutes of Health serum tray(s); and,
- (3) All potential recipient sera shall be screened monthly for cytotoxic antibodies against histocompatibility antigens.

(B) The tests in 105 CMR 180.430(A)(2) and (3) are required for transfusions and bone marrow transplants.

(C) For disease associated antigens, 105 CMR 180.430(A)(2) applies only to those antigens for which testing is performed.

(D) Mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens shall be performed in accordance with prescribed methods. Procedures shall be established for freezing of lymphocytes and to provide for a comprehensive panel of fresh and/or frozen lymphocytes.

(E) Procedures shall be established for the performance of cell harvesting, viability testing and purity checks on lymphocyte suspensions. Such checks shall be done for each test performed.

(F) Provisions for twenty-four hour laboratory coverage shall be maintained for organ transplant testing.

(G) The laboratory shall also:

- (1) At least once each month give each individual performing tests a individual's ability to reproduce test results. The results of such testing shall be recorded; and

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(2) Participate in at least one national or regional cell exchange program if available or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

180.450: Condition - Proficiency Evaluation

All clinical laboratories shall successfully complete an approved proficiency testing program covering all clinical laboratory and anatomical pathology specialties and subspecialties in which the laboratory is licensed or authorized to perform tests and in which there is a proficiency testing program available.

180.455: Standard - Proficiency Test Program Participation

(A) The laboratory shall participate in an approved proficiency testing program which adequately covers the level of services offered.

(B) The laboratory shall authorize the approved proficiency testing service to report all proficiency test results to the Department.

(C) The laboratory shall maintain proficiency testing results in each of the categories or subcategories which it is authorized or licensed to perform. These records shall be available to the Department and shall be kept on file for two years.

(D) The laboratory shall test applicable proficiency testing materials only in the laboratory to which the license and proficiency test requirements applies using personnel, equipment and reagents routinely used in that facility.

(E) An exception to the requirements of this section may occur if the Department determines that an appropriate proficiency testing program is not readily available. If a proficiency testing program acceptable to the Department is developed for a specialty or subspecialty in which no previous program had been approved, the clinical laboratory shall have one year in which to enroll.

(F) All clinical laboratories requesting licensure shall show evidence that they have enrolled in a proficiency testing program acceptable to the Department.

(G) The laboratory must select an appropriate service approved by the Department which has the ability to evaluate the specific laboratory methodology and/or instrumentation.

180.460: Standard - Successful Participation

Successful or satisfactory participation for individual analytes, specialties and subspecialties in proficiency testing shall be determined as follows:

(A) **Analytes:** The determination of satisfactory performance for each analyte shall be based upon the achievement of results within the acceptable limits established by the proficiency testing service for that procedure or by other criteria approved by the Department.

(B) **Specialty/Subspecialty:** The determination of satisfactory performance for each specialty or subspecialty shall be based upon the average score for all analytes within that specialty or subspecialty. The Department shall develop and publish criteria for defining the minimum acceptable average performance for each specialty or subspecialty.

(C) Unsatisfactory participation for two successive proficiency tests for an analyte, a specialty, or a subspecialty may result in a request for a plan of correction.

(D) Unsatisfactory performance in a specialty or subspecialty for three consecutive or three out of the last four consignments, may result in revocation or limitation of a license for that specialty or subspecialty area. If a license is revoked or limited for reasons of unsatisfactory performance, reinstatement shall require demonstration of satisfactory proficiency over a period of two consignments, not to exceed six months.

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(E) The laboratory shall maintain records of interpretation and remedial actions taken when proficiency testing results are determined to be unsatisfactory.

180.475: Severability

The provisions of 105 CMR 180.000 are severable. If any provision shall be declared invalid by any court, such provision shall be null and void and such determination shall not affect or impair any of the remaining provisions.

REGULATORY AUTHORITY

105 CMR 180.000: M.G.L. c. 111, § 3; c. 111D; c. 111 §§ 51 through 53.

(105 CMR 181.00 THROUGH 199.00 RESERVED)